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Re-evaluation Decision RVD2014-07

Nucleopolyhedrovirus for Gypsy Moth Larvae

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Re-evaluation Decision

Nucleopolyhedrovirus for gypsy moth larvae – that is, *Lymantria dispar* multicapsid nucleopolyhedrovirus (LdMNPV) – is a naturally occurring baculovirus, which is used as a microbial pest control agent for the suppression of gypsy moth populations in North America. There are two products containing LdMNPV that are currently registered in Canada under the authority of the *Pest Control Products Act*, including one technical grade active ingredient and one restricted class end-use product.

After a re-evaluation of LdMNPV Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, is granting continued registration of products containing LdMNPV for sale and use in Canada. An evaluation of available scientific information found that products containing LdMNPV do not present unacceptable risks to human health or the environment when used according to the conditions of registration, which include amended label directions. LdMNPV was found to have value as a microbial insecticide for the suppression of gypsy moth populations in North America. As a condition of the continued registration of LdMNPV, label amendments are required. Appendix I lists the required label amendments. No additional data are requested at this time.

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2012-02, *Re-evaluation Program Cyclical Re-evaluation*, presents the details of the cyclical re-evaluation approach, which is in line with the requirements of the *Pest Control Products Act*. Re-evaluation draws on data from registrants, published scientific reports, information from other regulatory agencies and any other relevant information available.

This re-evaluation decision,[1] previously proposed in the consultation document, Proposed Re-evaluation Decision PRVD2013-02, *Nucleopolyhedrovirus for Gypsy Moth Larvae*, describes the decision-making stage of the PMRA's regulatory process and summarizes the Agency's decision and the reasons for it. No comments were received during the consultation process. Therefore, this decision is consistent with the proposed re-evaluation decision stated in PRVD2013-02. Please refer to both the Overview and more detailed Science Evaluation sections of PRVD2013-02 for the human health, environmental and value considerations underlying this re-evaluation decision. A reference list for all data used as the basis for the re-evaluation decision is also included in PRVD2013-02.

To comply with this decision, the registrant of LdMNPV products will be informed of the specific requirements affecting their product registration(s) and of the regulatory options available to them.

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[1] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Other Information

Any person may file a notice of objection[2] regarding this decision on LdMNPV within 60 days from the date of publication of this Re-evaluation Decision document. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

[2] As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Label Amendments for Products Containing LdMNPV

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the following label statements.

The labels must be amended to include the following statements to further protect workers and the environment.

I) On the principal display panel of both the technical product and the end-use product labels, the following hazard signal words must be included:

CAUTION – EYE IRRITANT

POTENTIAL SENSITIZER

II) On the secondary display panel of both the technical and end-use product labels the following must be removed:

FIRST AID:

In case of contact with skin or eyes, flush with water. If irritation or sensitization occurs and persists, seek medical attention, or contact Poison Control Centre immediately. Take container, label or product name and Pest Control Registration Number with you when seeking medical attention.

And replaced with:

FIRST AID:

If swallowed: Call a poison control centre or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control centre or doctor. Do not give anything by mouth to an unconscious person.

If on skin/clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15–20 minutes. Call a poison control centre or doctor for treatment advice.

If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control centre or doctor for further treatment advice.

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control centre or doctor for treatment advice.

General: Take container, label or product name and Pest Control Product Registration Number with you when seeking medical attention.

TOXICOLOGICAL INFORMATION: Treat symptomatically.

III) In the **PRECAUTIONS** section of the end-use product label the following must be removed:

When handling this product and spray mixtures, gloves, a dust mask or appropriate respirator, and goggles should be worn.

And replaced with:

Mixers and loaders: Wear a long-sleeved shirt, long pants, shoes plus socks, waterproof gloves and a dust/mist filtering respirator/mask (NIOSH approval number prefix TC-21) or NIOSH approved respirator with any N-95, R-95, P-95 or HE filter for biological products when mixing and loading the product and during clean-up/repair activities. Wash thoroughly with soap and water after handling.

IV) In the **PRECAUTIONS** section of the end-use product label the following statements must be removed:

To avoid bystander exposure people should not enter treated areas during application and for 1 hour following the application.

Avoid contamination of water bodies during cleaning of equipment or disposal of waste.

V) The following wording must appear on the secondary display panel of the end-use product label and be circumscribed by a line (in other words, wording must appear in a box):

RESTRICTED USES
FORESTRY

NOTICE TO USER: This pest control product is to be used only in accordance with the directions on the label. It is an offence under the *Pest Control Products Act* to use this product in a way that is inconsistent with the directions on the label. The user assumes the risk to persons or property that arises from any such use of this product.

NATURE OF RESTRICTION: This product is to be used only in the manner authorized; consult local provincial pesticide regulatory authorities about use permits that may be required.

RESTRICTED USE: For use by or under the direct supervision of the Canadian Forest Service in government sponsored gypsy moth management programs; for aerial application only in forests and woodlands management.

Mode of action: Disparvirus is highly specific to gypsy moth larvae. The active ingredient in Disparvirus is an insect virus that is contained within polyhedral inclusion bodies. These inclusion bodies must be eaten by susceptible larvae to cause infection. The protein of the inclusion bodies dissolves in the insect gut releasing the infectious virus particles which then penetrate gut cells and start the cycle of virus infection. The virus replicates exclusively in the nucleus of susceptible insect cells. Death occurs in about 15 days.

This product is active only on gypsy moth larvae. To prevent defoliation where significant populations of other leaf chewing larvae are present, use of other registered products is necessary.

DIRECTIONS FOR USE

Apply only by fixed wing or rotary wing aircraft equipment which has been functionally and operationally calibrated for the atmospheric conditions of the treatment area and the application rates and conditions of this label. Consult the local Transport Canada office regarding low level flying regulations.

Read and understand the entire label before opening and mixing this product. Apply only at the rate recommended for aerial application.

Disparvirus is recommended for treatment of moderate density populations of gypsy moth. When used precisely according to the dose, timing and application instructions specified below, Disparvirus treatment of moderate gypsy moth populations may result in protection of oak foliage of at least 55-60% and reductions in egg mass density. The extent of egg mass density reduction and the need for retreatment in the following year is influenced by many variables, especially the pre-spray egg mass density and the health of the gypsy moth population. Disparvirus is not recommended for use where the goal of aerial application is eradication of gypsy moth. Results of treatment may be unsatisfactory if egg hatch is significantly extended or when pre-spray populations exceed 10,000 egg masses per hectare.

Dose and Timing for Aerial Application

Disparvirus should be applied 2 times, at a dosage of 5×10^{11} polyhedral inclusion bodies per hectare (PIBs/ha) per application (total 10^{12} PIBs/ha) in the specified spray mixtures, at an emitted volume of 5.0 L/ha with 3–4 days between applications. Timing of application is critical. Larvae should all be in their first

instar and actively feeding at the time of first application. At the time of second application, it is expected that about 50% of larvae will have reached their second instar. Oak leaves should be at least 50% expanded at the time of application. Thorough, well distributed spray coverage is necessary to ensure that feeding larvae ingest a lethal dose of Disparvirus. Aircraft fitted with rotary atomizers should be used and droplets should be in the 100–150 micron range. Avoid application when significant rainfall is anticipated.

Spray Mixtures

Disparvirus powder may be applied by air using the aqueous spray mixtures specified below. For an emitted volume of 5 litres per hectare, use ___grams of this batch of Disparvirus per hectare to be treated, so as to obtain a final concentration of 10^{11} PIBs per litre of spray mix. To prepare 100 litres of spray mix, add _____grams of this batch of Disparvirus to 10 litres of water and mix well to obtain a consistent, uniform slurry. Use of non-chlorinated water is preferred. If only chlorinated water is available, it must be allowed to stand for 24 hours before mixing with Disparvirus.

Commercial Carrier: Prepare 100 litres of aqueous formulation by adding the 10 litres of Disparvirus aqueous slurry to 90 litres of Carrier 038 (Abbott Laboratories). This spray mix should be discarded if not used within 24 hours of mixing. Although field trials have not been conducted with Disparvirus in this carrier, it is expected to perform as well as the basic spray mix. Consult the manufacturer (Abbott Laboratories) for advice regarding handling, mixing and aerial application of the carrier. Increased viscosity of the carrier may occur at low (<6°C) temperatures.

Basic Spray Mix: To prepare 100 litres of basic spray mix, add a further 62 litres of water and 6.0 kg Orzan LS (I.T.T. Rayonier, Seattle, WA) to the 10 litres of Disparvirus aqueous slurry. **MIX THOROUGHLY**. The Orzan LS is essential as an ultraviolet protectant. Then add 25 litres of animal feed grade molasses and 2.0 litres of Bond sticker (Loveland Industries, Greeley, CO). This spray mix should be discarded if not used within 12 hours of mixing.

This product should not be mixed with any materials other than those listed on this label.

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

As this product is not registered for the control of pests in aquatic systems, **DO NOT** use to control aquatic pests.